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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,831	01/03/2001	Hermann Oppermann	STK-008CN	3498

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TESTA, HURWITZ & THIBEAULT, LLP
HIGH STREET TOWER
125 HIGH STREET
BOSTON, MA 02110

EXAMINER

KEMMERER, ELIZABETH

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/754,831	Applicant(s) OPPERMANN ET AL.	
	Examiner Elizabeth C. Kemmerer, Ph.D.	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 81-91 is/are pending in the application.
- 4a) Of the above claim(s) 84 and 86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 81-83, 85 and 87-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/10/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (claims 81-83, 85, and 87-91 (in part), in the reply filed on 29 July 2004 is acknowledged. The traversal is on the ground(s) that the nucleic acid sequence recited in Group II claims include the nucleic acid sequences recited in Group I claims; the amino acid sequences recited in Group I and Group II claims include the amino acid sequence recited in Group III claims; the Groups are all classified as belonging to the same class (536/23.1), and a search for art relating to the claims of one Group will reveal art, if any, relating to the other Groups. This is not found persuasive because there is no clear structural relationship between the different sequences. No alignment was provided, for example. A visual comparison of the sequences presents no immediately discernable structural relationship. Therefore, a separate search of the sequence and literature databases must be made for each sequence, resulting in an undue burden should the sequences be kept in one group.

The requirement is still deemed proper and is therefore made FINAL.

Claims 84 and 86 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 29 July 2004.

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Status of Application, Amendments, And/Or Claims

The preliminary amendment of 25 March 2003 has been entered in full. Claims 1-80 are canceled. Claims 84 and 86 are withdrawn from consideration as being directed to a non-elected invention, as set forth above. Claims 81-83, 85 and 87-91 are under examination to the extent that they read on the elected invention.

Sequence Rules

The application is not fully in compliance with the sequence rules, 37 CFR 1.821-1.825, because each disclosure of a sequence embraced by the definitions set forth in the rules is not accompanied by the required reference to the relevant sequence identifier (SEQ ID NO:). This occurs throughout the specification and Figures.

Specification

The disclosure is objected to because of the following informalities: There are inappropriate hand-written notations in the specification (see p. 10).

Appropriate correction is required.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

Claims 87-91 are objected to because of the following informalities: the claims depend in part from claims that are withdrawn from consideration, and thus read on non-elected inventions. Appropriate correction is required.

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 83, 85, 87-89 and 91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 83 recites molecular weight limitations. however, the method by which the molecular weight is to be determined is not recited. Molecular weight is a value that is entirely dependent upon the method by which it is measured. For example, a molecular weight of a protein determined by native gel analysis would be quite different from the molecular weight of the same protein determined under reducing conditions, or by calculation, or by gel filtration. Therefore, the limitation of molecular weight without reference to the method by which it is determined is meaningless. Claim 85 recites an isolated nucleic acid molecule comprising a nucleic acid sequence *consisting essentially of* nucleotides 34-324 of Fig. 1B. It is not clear what essential features of the recited sequence must be retained by a variant sequence in order to remain encompassed by the claim. Are deletions, insertions, and/or substitutions encompassed? Without knowing such details,

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the skilled artisan would be unable to determine the metes and bounds of the claimed invention. Claims 87-89 and 91 are directed to a host cell. It is not clear whether the claim is directed to isolated host cells or host cells in the context of multi-cellular transgenic organisms, possibly even humans. Amending these claims to recite an "isolated" host cell would be remedial.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) Claims 81-83, 85 and 87-91 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,261,835. Although the conflicting claims are not identical, they are not patentably distinct from each other because the isolated nucleic acid molecule recited in the pending claims is exactly the insert of the patented claims. It would have been obvious to one of ordinary skill in the art to isolate the insert of any vector. The host cells of the pending claims could be made by inserting the vectors of the patented

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claims. It would have been obvious to one of ordinary skill in the art to make the instant host cells, because the nucleic acid molecules can only be replicated in the context of a host cell.

2) Claims 81-83, 85 and 87-91 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 30 and 34 of U.S. Patent No. 6,071,695. Although the conflicting claims are not identical, they are not patentably distinct from each other because the DNA sequences recited in the instant claims are OP-1 DNA sequences, as are the OP-1 DNA sequence recited in the patented claims.

3) Claims 81-83, 85 and 87-91 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 9-18, 26-41 and 43-47 of U.S. Patent No. 5,863,758. Although the conflicting claims are not identical, they are not patentably distinct from each other because the specific OP-1 sequences recited in the patented claims are exactly the OP-1 sequences encompassed by the pending claims. The pending claims recite conservative variants, but such are obvious over the specific OP-1 sequences recited in the patented claims.

4) Claims 81-83, 85 and 87-91 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20 and 22 of U.S. Patent No. 5,712,119. Although the conflicting claims are not identical, they are not

patentably distinct from each other because the sequences recited in the pending claims encode the OP-1 protein recited in the patented claims. The cells of the patented claims recite more elements than the nucleic acid molecules and host cells of the instant claims; however, the instant claims recite open claim language, and thus the patented claims are a species of the instant generic claims. A species renders obvious its genus.

5) Claims 81-83, 85 and 87-91 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,670,336. Although the conflicting claims are not identical, they are not patentably distinct from each other because the nucleic acid molecules of the instant claims are exactly those used in the methods of the patented claims.

6) Claims 81-83, 85 and 87-91 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 5,652,118. Although the conflicting claims are not identical, they are not patentably distinct from each other because the OP-3 sequence recited in the patented claims is a conservative substitution variant of OP-1 as recited in the instant claim. A species renders obvious its genus.

7) Claims 81-83, 85 and 87-91 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-19 and 21 of

U.S. Patent No. 5,614,385. Although the conflicting claims are not identical, they are not patentably distinct from each other because the sequences of the instant claim encode the OP-1 recited in the patented claims.

8) Claims 81-83, 85 and 87-91 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-20, 22, 24, 53-55, 57 and 59 of U.S. Patent No. 5,585,237. Although the conflicting claims are not identical, they are not patentably distinct from each other because the sequences recited in the instant claims encode the OP-1 recited in the patented claims. The cells of the patented claims recite more elements than the nucleic acid molecules and host cells of the instant claims; however, the instant claims recite open claim language, and thus the patented claims are a species of the instant generic claims. A species renders obvious its genus.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Thursday, 7:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, Ph.D. can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ECK

Elizabeth C. Kenner

ELIZABETH KENNER
PRIMARY EXAMINER